only consider, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA approval or clearance by July 1 prior to the particular fiscal year.

[66 FR 46924, Sept. 7, 2001, as amended at 68 FR 45469, Aug. 1, 2003; 69 FR 49243, Aug. 11, 2004; 73 FR 48755, Aug. 19, 2008; 74 FR 43997, Aug. 27, 2009]

§412.88 Additional payment for new medical service or technology.

- (a) For discharges involving new medical services or technologies that meet the criteria specified in §412.87, Medicare payment will be:
 - (1) One of the following:
- (i) The full DRG payment (including adjustments for indirect medical education and disproportionate share but excluding outlier payments);
- (ii) The payment determined under §412.4(f) for transfer cases;
- (iii) The payment determined under $\S412.92(d)$ for sole community hospitals; or
- (iv) The payment determined under §412.108(c) for Medicare-dependent hospitals; plus
- (2) If the costs of the discharge (determined by applying the operating cost to charge ratios as described in §412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—
- (i) 50 percent of the costs of the new medical service or technology; or
- (ii) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.
- (b) Unless a discharge case qualifies for outlier payment under §412.84, Medicare will not pay any additional amount beyond the DRG payment plus 50 percent of the estimated costs of the new medical service or technology.

[66 FR 46924, Sept. 7, 2001, as amended at 67 FR 50111, Aug. 1, 2002; 69 FR 49244, Aug. 11, 2004; 72 FR 47411, Aug. 22, 2007]

PAYMENT ADJUSTMENT FOR CERTAIN REPLACED DEVICES

§ 412.89 Payment adjustment for certain replaced devices.

(a) General rule. For discharges occurring on or after October 1, 2007, the amount of payment for a discharge de-

scribed in paragraph (b) of this section is reduced when—

- (1) A device is replaced without cost to the hospital;
- (2) The provider received full credit for the cost of a device; or
- (3) The provider receives a credit equal to 50 percent or more of the cost of the device.
- (b) Discharges subject to payment adjustment. (1) Payment is reduced in accordance with paragraph (a) of this section only if the implantation of the device determines the DRG assignment.
- (2) CMS lists the DRGs that qualify under paragraph (b)(1) of this section in the annual final rule for the hospital inpatient prospective payment system.
- (c) Amount of reduction. (1) For a device provided to the hospital without cost, the cost of the device is subtracted from the DRG payment.

[72 FR 47411, Aug. 22, 2007]

Subpart G—Special Treatment of Certain Facilities Under the Prospective Payment System for Inpatient Operating Costs

§412.90 General rules.

- (a) Sole community hospitals. CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available in a geographic area to Medicare beneficiaries. If a hospital meets the criteria for such an exception under §412.92(a), its prospective payment rates for inpatient operating costs are determined under §412.92(d).
- (b) Referral center. CMS may adjust the prospective payment rates for inpatient operating costs determined under subpart D or E of this part if a hospital acts as a referral center for patients transferred from other hospitals. Criteria for identifying such referral centers are set forth in §412.96.
 - (c) [Reserved]
- (d) Kidney acquisition costs incurred by hospitals approved as renal transplantation centers. CMS pays for kidney acquisition costs incurred by renal